Innovate in India for Inclusiveness (P156241)

SOUTH ASIA | India | Finance, Competitiveness and Innovation Global Practice | IBRD/IDA | Investment Project Financing | FY 2017 | Seg No: 7 | ARCHIVED on 27-Nov-2020 | ISR44119 |

Implementing Agencies: India, Biotechnology Industry Research Assistance Council

#### **Key Dates**

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Bank Approval Date: 31-May-2017 Effectiveness Date: 23-May-2018

Planned Mid Term Review Date: 07-Oct-2020 Actual Mid-Term Review Date: 26-Oct-2020

Original Closing Date: 30-Jun-2023 Revised Closing Date: 30-Jun-2023

### **Project Development Objectives**

Project Development Objective (from Project Appraisal Document)

The proposed project development objective (PDO) is to facilitate innovation in biopharmaceutical products and medical devices that address public health priorities in India

Has the Project Development Objective been changed since Board Approval of the Project Objective?

Public Disclosure Authorized

### Components

Name

Strengthening the pilot-to market innovation ecosystem: (Cost \$125.00 M) Accelerating the pilot-to-market process for specific products:(Cost \$120.00 M) Project management:(Cost \$5.00 M)

### **Overall Ratings**

Name	Previous Rating	Current Rating
Progress towards achievement of PDO	□ Moderately Satisfactory	□Satisfactory
Overall Implementation Progress (IP)	□Moderately Satisfactory	□ Moderately Satisfactory
Overall Risk Rating	□Substantial	Substantial

## Implementation Status and Key Decisions

The project is making satisfactory progress in achieving its outcome indicators. Three out of the five outcome indicators have achieved end of project targets, including: 32 intellectual property (IP) registrations or product prototypes, 13 technologies licensed for manufacturing or commercialization, and 19 products that address public health priorities advancing at least one step on the product development pathway. The remaining two indicators have achieved their FY21 targets, with the establishment of 5 technology transfer offices and 57 companies using the shared facilities supported by the project.

Over 90 percent of project funds have been committed in INR. Nearly 80 percent of commitments have already been signed through Grant-in-Aid Letter Agreements (GLAs), with the remaining 20 percent expected by the end of 2020. The project's ecosystem (Component 1) includes support for 21 shared facilities (average INR 192m/U\$2.6m), 29 scientific research (average INR 34.8m/U\$\$0.5m), 16 clinical trial networks (average INR 87.8m / US\$1.2), and 7 technology transfer offices (average INR 97.7m/US\$1.3m). The project's product portfolio includes support for the

11/27/2020 Page 1 of 6 development of 22 vaccines (average INR 103.3m/US\$1.4m), 27 biosimilars (average INR 111.9m/US\$1.5m), and 33 medical devices and diagnostics (average INR 23.6m/US\$0.3m).

The project's success in identifying and funding the biotech ecosystem together with a large product portfolio will need a redefinition of project's progress toward its development objective. The reach of many Project Development Objective indicator targets at mid-term review means that new measures of project success are needed for actionability during the second half of the project. This is especially important as the product portfolio is about 10 times larger than originally envisioned. This will require BIRAC's close monitoring and facilitation support to maximize the chances of products reaching the market to address India's public health priorities.

#### **Risks**

#### **Systematic Operations Risk-rating Tool**

Risk Category	Rating at Approval	Previous Rating	Current Rating
Political and Governance	□Low	□Low	□Low
Macroeconomic	□Low	□Moderate	□Moderate
Sector Strategies and Policies	□Moderate	□Moderate	□Moderate
Technical Design of Project or Program	Substantial	Substantial	Substantial
Institutional Capacity for Implementation and Sustainability	Moderate	Substantial	Substantial
Fiduciary	□Moderate	□Moderate	Moderate
Environment and Social	□Low	Low	□Low
Stakeholders	□Low	Low	□Low
Other		□Moderate	□Moderate
Overall	Substantial	□Substantial	Substantial

#### Results

### PDO Indicators by Objectives / Outcomes

To facilitate innovation in biopharma & medical devices addressing public health priorities in India

▶ Number of products addressing public health priorities advanced at least one step on the product development pathway (Number, Custom)

	Baseline	Actual (Previous)	Actual (Current)	End Target
Value	0.00	7.00	19.00	6.00
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023

► Number of new IP registrations or product prototypes (Number, Custom)

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	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	13.00	32.00	15.00			
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023			
► Number of technologies licens	eed for manufacturing or com	mercialization (Number, Cus	tom)				
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	0.00	13.00	2.00			
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023			
► Number of TTOs established	(Number, Custom)						
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	5.00	5.00	6.00			
Date	14-Nov-2017	16-Apr-2020	04-Nov-2020	01-May-2023			
►Number of companies using shared facilities supported by the project (Number, Custom)							
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	14.00	57.00	60.00			
Date	14-Nov-2017	16-Apr-2020	04-Nov-2020	01-May-2023			

# **Intermediate Results Indicators by Components**

Strengthening the pilot-to market innovation ecosystem									
►Number of clinical trial sites that are GCP compliant (Number, Custom)									
	Baseline Actual (Previous) Actual (Current) End Target								
Value	0.00	0.00	11.00	5.00					
Date	14-Nov-2016	16-Apr-2020 04-Nov-2020 01-May-2023							
►Number of registered tech	nnology transfer professiona	ls qualified (Number, Custom)							
	Baseline	Actual (Previous)	Actual (Current)	End Target					
Value	0.00	11.00	15.00	12.00					
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023					

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Number of people trained (N	Number, Custom)			
	Baseline	Actual (Previous)	Actual (Current)	End Target
lue	0.00	1,183.00	1,406.00	1,775.00
ite	14-Nov-2017	16-Apr-2020	04-Nov-2020	01-May-2023
□Number of people trained	who are women (Percenta	ge, Custom Supplement)		
	Baseline	Actual (Previous)	Actual (Current)	End Target
/alue	0.00	31.00	37.00	50.00
aluc	0.00	31.00	37.00	50.0

Accelerating the pilot-to-	market process for specific prod	lucts					
►Number of product de	evelopment agreements in place	(Number, Custom)					
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	61.00	104.00	9.00			
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023			
► Number of international publications (Number, Custom)							
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	2.00	11.00	10.00			
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023			
► Proportion of grievand	ces responded to and/or resolve	d within the stipulated service	standards for response time	es (Percentage, Custom)			
	Baseline	Actual (Previous)	Actual (Current)	End Target			
Value	0.00	100.00	100.00	90.00			
Date	14-Nov-2016	16-Apr-2020	04-Nov-2020	01-May-2023			
Comments:		e queries from respondents to sal rejections or further repres					

## **Performance-Based Conditions**

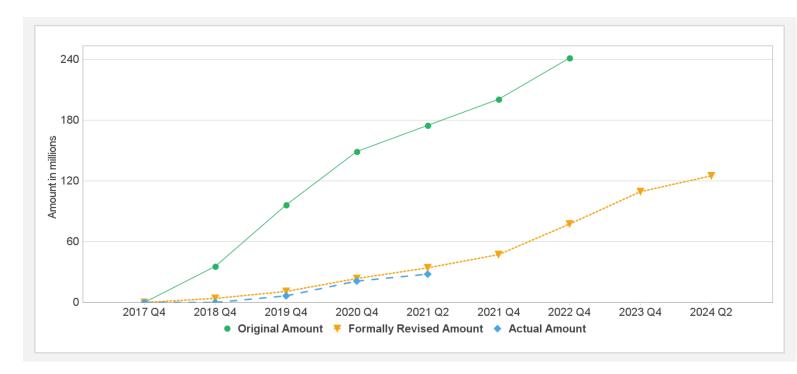
# **Data on Financial Performance**

# Disbursements (by loan)

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Project	Loan/Credit/TF	Status	Currency	Original	Revised	Cancelled	Disbursed	Undisbursed	% Disbu	ursed
P156241	IBRD-87510	Effective	USD	125.00	125.00	0.00	28.01	96.99		22%
Key Dates	Key Dates (by Ioan)									
Project	Loan/Credit/TF	Status	Approval Dat	e Signii	ng Date	Effectiveness D	ate Orig.	Closing Date	Rev. Closing Date	Э
P156241	IBRD-87510	Effective	31-May-2017	24-Ap	or-2018	23-May-2018	30-Ju	n-2023	30-Jun-2023	

### **Cumulative Disbursements**



## **PBC Disbursement**

PBC ID	PBC Type	Description	Coc	PBC Amount	Achievement Status	Disbursed amount in Coc	Disbursement % for PBC

# **Restructuring History**

There has been no restructuring to date.

# Related Project(s)

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There are no related projects.

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